In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-503V
Filed: October 12, 2023

MAYRA DEL BOSQUE, as parent and natural guardian of M.R., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for petitioner.
Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for respondent.

Findings of Fact and Conclusions of Law[1]

On April 27, 2020, the above captioned petitioner, Mayra Del Bosque, filed a petition on behalf of her minor child, M.R., under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa, *et seq.* (2012),[2] alleging that M.R.'s receipt of pneumococcal conjugate ("PCV"); *Haemophilus influenzae* type b ("Hib"); hepatitis A ("hep A"); measles, mumps, and rubella ("MMR"); and varicella vaccinations on November 7, 2017, caused M.R. to suffer immune thrombocytopenic purpura ("ITP"). (ECF No. 1, p.1.) For the reasons discussed below, I now find that there is preponderant evidence that onset of M.R.'s ITP occurred within 42 days of vaccination, but there is not preponderant evidence that onset occurred within 30 days of vaccination.

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Procedural History

Petitioner initially submitted medical records, marked Exhibits P1, P3, and P4. (ECF No. 6.) In addition, petitioner submitted an affidavit, marked Exhibit P2. (ECF No. 6.) Petitioner later filed additional medical records, marked Exhibits P5 through P8. (ECF Nos. 10, 13, 18, 22.) On April 13, 2021, respondent filed his Rule 4(c) Report and concluded that the case is not appropriate for compensation, raising issues relative to the timing of onset as well as evidence of an antecedent infection. (ECF No. 25.) Thereafter, petitioner filed an expert report by Abhimanyu Ghose, M.D., a hematologist and oncologist, marked Exhibit P9, with accompanying medical literature, marked Exhibit P11 through P11. (ECF Nos. 28-29.) Dr. Ghose opined that M.R. developed ITP as a result of the vaccinations he received on November 7, 2017. (Ex. P9, pp. 8-9.) Respondent filed a report by John Strouse, M.D., Ph.D., a pediatric hematologist and oncologist, marked Exhibit A, with accompanying medical literature, marked Exhibits A-1 through A-12. (ECF No. 32.) Dr. Strouse opined that M.R.'s vaccination was not the cause of his ITP. (Ex. A, p. 4.)

A Rule 5 status conference was held on January 4, 2022. (ECF No. 33.) During this conference, I noted that a Table claim of ITP following MMR vaccination requires an onset within 30 days post-vaccination; however, respondent's expert, Dr. Strouse, indicated that an onset period of up to 42 days post-vaccination could be medically appropriate to infer causation. (*Id.* at 1.) My preliminary view was that "petitioner's testimony, the medical records, and expert opinions, can very likely be harmonized to place onset of M.R.'s ITP within 42 days of his MMR vaccination, timing that is consistent with a causal inference." (*Id*. at 2.) That is, petitioner could potentially meet her *prima facie* burden under *Althen* and thereby shift the burden of proof to respondent with respect to demonstrating any factor unrelated to vaccination as the cause of M.R.'s ITP. (*Id*.)

On February 28, 2022, petitioner filed a supplemental report by Dr. Ghose, marked Exhibit P13. (ECF No. 34.) Petitioner then filed additional medical records marked Exhibits P14 through P15. (ECF Nos. 35.) On May 26, 2022, respondent filed a supplemental report by Dr. Strouse, marked Exhibit C, with accompanying medical literature marked Exhibit C-2. (ECF No. 38.) Thereafter, petitioner filed further medical records marked Exhibits P16 through P18. (ECF No. 39.) The parties then proposed proceeding with a mutually agreeable briefing schedule for written submissions, but ultimately disagreed on the scope of the issue presented. (ECF Nos. 40, 41.)

On July 1, 2022, petitioner filed a Motion for a Ruling on the Record. (ECF No. 42.) In her motion, petitioner requested a finding as to her entitlement to compensation, but also requested an opportunity to seek a hearing should the parties' briefs raise any issue that would warrant a hearing. (*Id*. at 4.) Respondent filed a response to this motion on September 13, 2022. (ECF No. 45.) In his response, respondent requested that my ruling be limited to onset only and not reach the question of entitlement. Respondent sought to reserve the right to provide additional briefing on entitlement at a later date. (*Id*. at 3.) Petitioner replied to this response on September 27, 2022, in

which she urged that I disregard respondent's objection and rule as to all issues. (ECF No. 46.)

II. Scope of this Fact Finding and Party Contentions

In light of the above, I have concluded that the parties have had a full and fair opportunity to develop the record with respect to onset *only*. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *see also Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (explaining that the Vaccine Act requires special masters to determine whether hearings or witness testimony are reasonable and necessary before ruling on the record). Petitioner's arguments regarding the sufficiency of the record for a ruling as to entitlement are significantly undercut by her own stated interest in maintaining the right to request an entitlement hearing. (ECF No. 42, p. 4). Moreover, petitioner heavily emphasizes my prior Rule 5 Order, but as respondent urges, that was a preliminary discussion only and I noted that the timing of onset was significant to Dr. Strouse's opinion in particular. (*Id.*; ECF Nos. 33, p. 1; 45, p. 3; 46.) Because the parties' experts reasonably came to differing assessments of onset based on the limitations of the evidence, I will provide the parties an opportunity to have their experts present supplemental reports setting forth their opinions *based on the facts as I have now found them*.[3] Thereafter, I anticipate resolving entitlement expeditiously and likely based on the written record.

Regarding onset, petitioner argues that onset of ITP was evidenced by M.R.'s history of easy bruising which she contends began two weeks post-vaccination. (ECF No. 42, pp. 35.) She further contends that, even accounting for respondent's expert's assessment of when the bruising began, onset of ITP was still within 42 days of M.R.'s vaccinations. (*Id*. at 37-38.) Respondent disputes that M.R.'s ITP was the cause of his bruising. (ECF No. 45, p. 24.) Accordingly, respondent asserts there is no evidence M.R. suffered ITP prior to the date of his first blood test on January 2, 2018, which was 56 days post-vaccination. (*Id*. at 23-26.) Additionally, respondent contends petitioner's description of M.R.'s bruising within her affidavit is uncorroborated and contradicted by the medical records. (*Id*. at 18, 22, 24-25.)

[3] *See Burns ex rel. Burnes v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that "[t]he special master concluded that the expert based his opinion on facts not substantiated by the record," and "[a]s a result, the special master properly rejected the testimony of petitioner's medical expert"); *see also Rickett v. Sec'y of Health & Human Servs.,* 468 Fed. App'x 952, 958 (Fed. Cir. 2011) (holding that "it was not error for the Special Master to assign less weight to Dr. Bellanti's conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett's testimony that was inconsistent with the medical records"); *Dobrydnev v. Sec'y of Health & Human Servs.,* 566 Fed. App'x 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion" (alteration in original) (quoting *Dobrydnev v. Sec'y of Health & Human Servs.*, No. 04-1593V, 2010 WL 8106881, at *9 n.12 (Fed. Cl. Spec. Mstr. Oct. 27, 2010), *aff'd*, 556 Fed. App'x 976 (Fed. Cir. 2014))).

III. Factual History

a. As reflected in medical records

M.R. was born on October 31, 2016. (Ex. P5, p. 125.) M.R.'s mother had a typical pregnancy and gave birth to twins by a Cesarean section. (*Id.*; Ex. P7, p. 79.) M.R.'s newborn screening was normal. (Ex. P6, pp. 521-804.) On the day he was born, M.R. received the newborn hepatitis B vaccine with no adverse reaction. (*Id.* at 537, 741.)

M.R. was a relatively healthy newborn. He was seen for a cough on November 22, 2016, and January 3, 2017. (Ex. P1, pp. 9, 10.) M.R. experienced some formula intolerance along with other gastrointestinal problems and was eventually diagnosed with gastroesophageal reflux disease ("GERD"). (*Id.* at 13.) At his six-month wellness check on May 30, 2017, M.R. received his hepatitis B; diphtheria, tetanus, acellular pertussis ("DTaP"); Hib; polio ("IPV"); PCV; and rotavirus vaccinations. (*Id.* at 19.) At his nine-month wellness check on August 14, 2017, M.R. received his influenza ("flu"), rotavirus, PCV, and IPV vaccinations. (*Id.* at 24.)

On September 8, 2017, M.R. was diagnosed with bronchiolitis. (*Id.* at 25.) On October 2, 2017, M.R. was diagnosed with an upper respiratory infection. (*Id.* at 29.) At his 12-month wellness check on November 7, 2017, M.R. received the set of vaccinations at issue in this case, which included the Hib, PCV, varicella, hep A, and MMR vaccines. (*Id.* at 26.)

Later that same month, on November 22, 2017, M.R. was brought to his pediatrician with complaints of cough, fever, and a swollen groin area, although he had no fever at the time he was seen. (*Id.* at 30.) He was again diagnosed with an upper respiratory infection. (*Id.*) Although petitioner's affidavit suggests M.R. had bruising at that time, this was not reported in the medical record. (*Compare* Ex. P2, p. 3, *with* Ex. P1, p. 30.)

M.R. returned to his pediatrician with a chief complaint of fever on December 8, 2017, but with a normal temperature upon presentation. He had redness in his throat and was diagnosed with pharyngitis. (Ex. P1, p. 31.) A three-day course of Zithromax was prescribed. (*Id.*) Again, although petitioner's affidavit indicates M.R. was experiencing bruising at this point in time, bruising is not documented in the December 8, 2017 medical record. (*Compare* Ex. P2, p. 3, *with* Ex. P1, p. 30.)

On January 3, 2018, M.R. was seen by his pediatrician with a history of present illness concerning "bruising mainly on legs." (Ex. P1, p. 32.) In advance of the appointment, blood was drawn on January 2, 2018. M.R.'s platelet count was 51,000, significantly below the reference range of 200,000-550,000/mcL. (Ex. P6, p. 472.) In seeking the bloodwork, M.R.'s pediatrician suspected anemia (*Id.* at 457); however, after the testing and examination M.R. was diagnosed with leukopenia and "thrombocytopenia, unspecified" (Ex. P1, p. 32.). Repeat bloodwork was ordered and

M.R. was referred to hematology. (*Id.*) On January 4, 2018, M.R.'s repeat platelet count was higher, but again lower than the reference range, at 97,000. (Ex. P6, p. 450.)

On January 14, 2018, M.R.'s mother noticed M.R. was bleeding from the mouth. (Ex. P6, pp. 367, 370, 380-81.) She took him to the hospital where he was first triaged at around 11:00pm and was observed to have torn upper lip and small hematoma, but no active bleeding. (*Id.*) He also had mild petechiae of his forehead, upper torso, and neck.[4] His platelet count was 4,000. (*Id.*) M.R. was transferred to the children's hospital on January 15, 2018. (Ex. P3, p. 6.) Petitioner reported that M.R. had been undergoing evaluation since early January for easily bruising, but the history is not explicit regarding when the bruising began. (*Id*. at 10.) Specifically, a history provided by petitioner recorded that

> In early January, patient was evaluated by his pediatrician due to a concern for bruising, per mother. Mother was confused because the patient seemed to bruise easily, however his twin sister had never experienced similar bruising. His pediatrician did a workup on 1/2, revealing a low white blood cell count, low platelets of 51k, high monocytic ratio, with a PT/PTT/INR that was normal. He underwent follow-up blood work on 1/4 and was noted to have an increased RBC count, a normal WBC count, and platelet that had increased from 51k to 97k. . . . The patient was scheduled to undergo follow-up lab work 3 weeks later, however P [*sic*] patient experienced this incident with bleeding of the mouth last night was brought to the Laredo ER and subsequently transferred to us for further management.

(*Id*.)

A separate history recorded the same morning further indicated that "[m]om states that on 1/1/18 she noticed red 'pinpoint perfect circles' over his skin, and could feel a [*sic*] little balls and lumps under some of them. . . . Mom states rash on skin and bruises that were noted at beginning of the month had resolved until last night." (*Id*. at 24.) This history further indicated that "[m]om states patient has not cried or shown that he was hurting prior to seeing his mouth bleeding. No increased irritability or fussiness. No prior abnormal bleeding or bruising." (*Id*.)

M.R. was assessed as having "a past medical history and current presentation consistent with immune thrombocytopenia of childhood." (*Id*. at 22.) Based on the presentation and increase in platelet counts on January 4, 2018, the treaters suggested that M.R.'s ITP initially self-resolved before recurring more severely. (*Id*. at 22, 26.) This was noted to be "slightly atypical." (*Id.* at 26.) The differential diagnoses included malignancy, bone marrow failure, acute viral infection, and autoimmune condition(s); however, these were all considered less likely given M.R.'s normal white and red blood

[4] Bruising was not documented as part of M.R.'s initial January 14, 2018 presentation at Doctor's Hospital of Laredo (Ex. P6, p. 370); however, it was documented the next day by Children's Hospital of San Antonio (Ex. P3, p. 12). He had scattered bruising over his upper extremities, trunk, and lower extremities. (*Id*.)

cell counts, lack of a clear viral prodrome, and lack of systemic symptoms. (*Id.* at 26-27.) It was noted, however, that "[s]ometimes in the setting of recent viral infections or other immune system triggers, ITP can be provoked" with about 15-20% of patients going on to have the chronic form of ITP. (*Id*. at 32.) M.R. was given 1 g/kg of IVIG treatment and his platelet count rose to 37,000. (*Id.* at 6.) He was eventually released on January 16, 2018. (*Id.* at 3.) While he was in the hospital, M.R. was given a flu shot. (*Id.* at 159.)

One week later, on January 26, 2018, M.R. had a follow up appointment with a hematology/oncology team. (*Id.* at 180.) It was noted that his platelets had again dropped below 10,000. (*Id*.) He was prescribed both 15 mg/5 mL prednisone and 15 mg/mL ranitidine. (*Id.* at 183.) On January 30, 2018, M.R. followed up with his pediatrician who requested bloodwork and recommended a follow up with the hematologist/oncologist in a week. (Ex. P1, p. 35.) M.R.'s platelet count was 154,000 on February 1, 2018. (Ex. P6, p. 359.) On February 8, 2018, M.R.'s dose of prednisone was decreased to 5 mL per day. (Ex. P3, p. 196.) His platelet count at this appointment was 64,000. (*Id.* at 195, 206.)

M.R. saw his pediatrician for his 15-month wellness check on February 13, 2018. (Ex. P1, p. 36.) He received his flu, DTaP, hep A, Hib, MMR, varicella, and PCV vaccinations. (*Id.* at 37.) On February 15, 2018, M.R. had a follow up with his hematologist. (Ex. P3, p. 202.) M.R.'s prednisone prescription was further tapered from 5mL per day to 3mL per day given that his platelet count had increased to 72,000 despite the prior reduction of his prednisone prescription to 5mL per day. (*Id.* at 200.) M.R. was seen again on February 22, 2018, and his platelets had increased to 337,000. (*Id.* at 202-05.) His prednisone was further tapered to 1mL per day. (*Id*. at 204.)

M.R. was seen again by his hematologist on March 8, 2023. (*Id.* at 211.) The hematologist recommended continuing M.R. on 1 mL of prednisone a day. (*Id.* at 212.) The plan was to wean off if M.R. could maintain a platelet count of greater than 30,000. (*Id.*) However, M.R.'s blood was drawn again on March 14, 2018, and platelet count had dropped to 12,000. (Ex. P6, p. 342.) M.R. was admitted to the hospital on March 16, 2018, and was given 1 gm/kg of IVIG treatment. (Ex. P3, p. 218.) M.R.'s blood was drawn again on March 21, 2018. (Ex. P6, p. 324.) After the IVIG treatment, M.R.'s platelet count was up to 50,000. (*Id.*)

On March 22, 2018, M.R. was seen by his pediatrician for a cough and congestion and to follow up on his labs. (Ex. P1, p. 39.) M.R. was diagnosed with sinusitis and rhinitis. (*Id.*) The next week, on March 29, 2018, M.R. was seen by Nurse Practitioner Jennifer Hemmeger. (Ex. P3, p. 323.) She noted that M.R. had completed his prednisone wean on March 26, 2018. (*Id*. at 324.) At this appointment, M.R. was showing symptoms, such as easy bruising and petechiae. (*Id.*) His platelet count was below 10,000. (*Id.*) M.R. was prescribed Win-Rho. (*Id.*)

On April 5, 2018, M.R. went to see his pediatrician for a follow up on his sinusitis and rhinitis. (Ex. P1, p. 40.) M.R.'s platelet count was 11,000. (*Id.*) On April 6, 2018,

M.R. was seen by hematology. (Ex. P3, p. 350.) M.R.'s ITP flare was not responding to Win-Rho and was thought to be a good candidate for Promacta. (*Id*. at 351.) On April 12, 2018, M.R.'s platelet count was still extremely low at 12,000. (Ex. P6, p. 291.) M.R.'s platelet count was slightly higher, but still low, at 46,000, on April 19, 2018. (*Id.* at 274.) M.R.'s platelet count dropped even lower, to 9,000, on April 30, 2018. (*Id.* at 257.)

Thereafter, Promatcta continued to be M.R.'s long term treatment plan. His platelet levels continued to fluctuate and he had additional periods where bruising was again reported as an issue. Although I have reviewed all of M.R.'s medical records, the further course of M.R.'s ITP is not illuminating as to the onset issue discussed herein. As of March 3, 2022, M.R.'s platelet count was 150,000 and he was doing well on 12.5 mg of Promacta per day. (Ex. P18, pp. 6, 14.)

b. As reflected in petitioner's affidavit

On May 8, 2020, petitioner submitted an affidavit, as the natural parent and legal guardian of M.R. (Ex. P2, ¶ 1.) Petitioner notes that M.R. was "healthy, active, and had no history of any conditions, diseases or disorders affecting his platelet counts or resulting in any bruising." (*Id.* ¶ 4.) Petitioner states that M.R. received PCV, Hib, hep A, MMR, and varicella vaccinations on November 7, 2017. (*Id.* ¶¶ 5 (citing Ex. P1, p. 27), 11.) According to the affidavit, approximately two weeks later, M.R. "started to develop bruising on his lower extremities, particularly on his calves." (*Id.* ¶ 12.) M.R. subsequently developed a cough and some congestion and petitioner took him to the doctor on November 22, 2017. (*Id.*) At this appointment, M.R.'s bruises were not discussed because petitioner believed these bruises were the result of M.R. falling when trying to walk. (*Id.*) (Petitioner's affidavit did not specifically address the December 8, 2017 encounter.)

In the middle of December 2017, petitioner noticed that M.R.'s bruising started to progress to his legs, armpits, arms, back of knees, and along his spine. (*Id.* ¶ 13.) Petitioner described the bruises as "very dark in color" and noted that some bruises had lumps associated with them. (*Id.*) Petitioner observed, "I could not figure out why my son was getting bruises in random spots of his body." (*Id.*) She explained that she "decided to keep a closer eye on any additional bruising in his body," further indicating that "[b]oth he and his sister were in the same walking and stumbling stage, both would be clumsy and fall quite often, and both would hit edges of furniture frequently. However, only my son, [M.R.], was getting more bruises than his twin sister." (*Id.*)

On January 3, 2018, petitioner took M.R. to be evaluated by his pediatrician. (*Id.* ¶ 14.) Subsequently, petitioner noticed excessive bleeding from M.R.'s mouth. (*Id.* ¶ 15.) Petitioner took M.R. to the emergency room on January 15, 2018. (*Id.* ¶ 16.) (The medical records reflect it was actually late on the 14th.) Blood results at the hospital confirmed that M.R. had a low platelet count and needed to be evaluated by a pediatric hematologist. (*Id.*) M.R. was transferred to a Children's Hospital via ambulance and was started on IVIG treatment. (*Id.*)

Over the next year, M.R. was readmitted to the hospital for a low platelet count. (*Id.* ¶ 18.) M.R. did not respond well to the treatments and would often pull his hair, bang his head, and hit or bite petitioner. (*Id.*) During this time, M.R. was treated with IVIG, WinRho, steroids, and platelet transfusions. (*Id.* ¶ 19.) In the summer of 2019, petitioner went to another physician who recommended chemotherapy if medication stopped working. (*Id.*)

Currently, M.R. continues to treat with Promacta, but he still bruises. (*Id.* ¶ 21.) He gets sick "frequently due to his compromised immune system and his fluctuating platelet count." (*Id.*)

IV. Expert Opinions

a. Petitioner's Hematology/Oncology Expert, Dr. Ghose [5]

Dr. Ghose provided two reports for this case. (Exs. P9, P13.) In his first report, Dr. Ghose began by summarizing M.R.'s medical history. (Ex. P9, p. 3-4.) He agrees with M.R.'s diagnosis of chronic ITP. (*Id.* at 7.)

In his first report, Dr. Ghose assumed that M.R. first experienced onset of bruising about two weeks post-vaccination as indicated in petitioner's affidavit. (*Id.* at 3, 7.) He opines that this is well within the timeframe for developing ITP post-vaccination. (*Id.* at 7.) He states that, generally, in cases of Secondary ITP due to vaccination, kids develop symptoms of ITP an average of 18 days following vaccination. (*Id.* (citing K. Ikegame et al., Letter to the Editor, *Idiopathic Thrombocytopenic Purpura After Influenza Vaccination in a Bone Marrow Transplantation Recipient*, 38 BONE MARROW TRANSPLANTATION 323 (2006) (Ex. P11(y)); Satoshi Mamori et al., Letter to the Editor, *Thrombocytopenic Purpura After the Administration of an Influenza Vaccine in a Patient with Autoimmune Liver Disease*, 77 DIGESTION 159 (2008) (Ex. P11(z))).) However, he also explained that cases of ITP following the MMR vaccine can develop within six weeks of vaccination. (*Id.* at 8.)[6] He opines that the early bruising that M.R. developed

[5] Abhimanyu Ghose, M.D., FACP, is a board certified hematologist and oncologist. (Ex. P10, p. 1.) He attended medical school at the University of Cincinnati, completed his residency in internal medicine at the University of Toledo Medical Center, and completed a fellowship in hematology and oncology at the University of Cincinnati. (*Id.*) He is currently employed at the Arizona Center for Cancer Care/Honor Health, and he both sees patients and participates in clinical research. (*Id.*) He has published 21 peer-reviewed articles. (Ex. P13, p.1; Ex. P10, p. 3-5.)

[6] In support of this conclusion, Dr. Ghose cites exhibits that he has labeled "32 and 33," however, this appears to be an error. His expert report only lists 28 exhibits and petitioner has only provided 28 exhibits to the court. Nonetheless, several other exhibits provided by petitioner support this conclusion, including: Valerio Cecinati et al., *Vaccine Administration and the Development of Immune Thrombocytopenic Purpura in Children,* 9 HUMAN VACCINES & IMMUNOTHERAPEUTICS 1158 (2013) (Ex. P12(b)); Annie P. Jonville-Bera et al., *Thrombocytopenic Purpura After Measles, Mumps, and Rubella Vaccination: A Retrospective Study by the French Regional Pharmacovigilance Centres and Pasteur-Merieux Serums et Vaccins,* 15 PEDIATRIC INFECTIOUS DISEASE J. 44 (1996) (Ex. P11(o)); and Corri Black

two weeks after vaccination is a "classic sign of ITP" and is "well within the time frame when symptoms of ITP develop following vaccination." (*Id.*) He opined that since M.R.'s ITP was untreated in November 2017, M.R.'s symptoms continued to worsen until his ITP was diagnosed and he began treatment on January 3, 2018. (*Id.*)

Dr. Ghose also places the drop in M.R.'s platelet count as occurring by mid-December, which correlates to the time when petitioner indicates she observed a wider progression of M.R.'s bruising. (*Id.*) He explained that "[t]he chronology of events in this situation supports what we typically see in a case of vaccine associated ITP. It would take a matter of weeks for M.R.'s platelets to go from normal down to 51,000 as confirmed on January 3, 2018. It would logically and medically flow that M.R.'s onset of ITP was at least several weeks prior to January 3, 2018." (*Id*.)

In his second report, Dr. Ghose addresses three topics in response to Dr. Strouse's report: onset, cause, and diagnosis. (Ex. P13.) With regard to onset, he reiterates his rationale that M.R.'s platelets would have dropped below normal range well prior to January 3, 2018. (*Id.* at 1-2.) Given petitioner's report of M.R. bruising first in November, and then later more severely in December, as well as the amount of time over which M.R.'s platelets would be expected to be dropping, Dr. Ghose confirms that his opinion, stated to a reasonable degree of medical certainty, is that M.R. was suffering ITP (*i.e.*, having a platelet count under 100,000) by no later than 42 days post-vaccination, which is consistent with the November 7, 2017 MMR vaccine being the cause of his ITP. (*Id*.)

b. Respondent's Hematology/Oncology Expert, Dr. Strouse[7]

Respondent's expert, Dr. Strouse also submitted two reports in this case. (Ex. A; Ex. C.) In his first report, Dr. Strouse summarizes M.R.'s medical record and ultimately agrees with his diagnosis of chronic ITP. (Ex. A. pp. 1-2, 4.) However, he stresses that M.R.'s initially mild presentation suggests his decrease in platelets was specifically due to decreased platelet production, likely resulting from viral infection. (*Id*. at 3.) He opines that, usually, ITP in children "presents with the rapid development of severe thrombocytopenia without other decreases in white blood cells . . . or red blood cells." (*Id.*) Dr. Strouse noted that M.R.'s ITP was unusual in that he initially had only a minor decrease in white and red blood cells. (*Id.*) However, Dr. Strouse notes that this short term decrease in both white and red blood cells is seen with viral suppression. (*Id.*) He attributed such viral suppression in M.R. to his pharyngitis, noting that "[v]iral infections are the most common cause of pharyngitis" in younger children. (*Id.*)

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et al., *MMR Vaccine and Idiopathic Thrombocytopaenic Purpura,* 55 BRIT. J. CLINICAL PHARMACOLOGY 107 (2003) (Ex. P11(n)).

[7] John J. Strouse, M.D., Ph.D. is a board certified pediatric hematologist and oncologist. (Ex. B, p. 1.) He is currently an Associate Professor of Medicine and Pediatrics and Director of the Adult Sickle Cell Program at Duke University. (Ex. A, p. 1.) Throughout his clinical practice, he has treated both children and adults with acute and chronic autoimmune thrombocytopenia. (*Id.*) He received both his M.D. and Ph.D. from Johns Hopkins University, and he has published 95 refereed journals. (Ex. B, pp. 2-9.)

Dr. Strouse agrees that the MMR vaccine can trigger ITP in young children up to 42 days post-vaccination. (*Id*.) However, he opines that onset of M.R.'s ITP is "unclear." (*Id.* at 4.) Dr. Strouse explains that mild thrombocytopenia (which he defines as a platelet count over 50,000) is often asymptomatic. (*Id*. at 3.) Instead, he suggests that the leg bruising petitioner described occurring in November 2017 may well have been related to the type of bruising typically seen in toddlers learning to walk. (*Id*. at 4.) And, although he acknowledges petitioner described increased bruising occurring about five to six weeks post vaccination, he stresses that thrombocytopenia was not actually documented until M.R.'s January 2, 2018 blood test showed low platelets with severe thrombocytopenia not being evidenced until mid-January, about ten weeks post-vaccination. (*Id*.) Therefore, he opines a viral infection (for which M.R. was seen on December 8, 2017) occurring about four weeks prior to onset is a more likely cause of the ITP. (*Id*.)

In his second report, Dr. Strouse discusses Dr. Ghose's assessment of "kinetics of changes in platelet count." (Ex. C, p. 2.) He suggests that the type of gradual decline in platelet counts that Dr. Ghose cites would be more likely seen in thrombocytopenia following triggers such as cytotoxic chemotherapy or bone marrow failure, rather than the immune mechanism at issue in ITP specifically. (*Id*.) Rather, in young children with ITP, the drop in platelets is "usually sudden." (*Id*.) Dr. Strouse suggests that M.R. experienced bruising five to six weeks post-vaccination at the earliest and then only mild thrombocytopenia about eight weeks post-vaccination. He believes it is unlikely that the thrombocytopenia caused M.R.'s increased bruising. (*Id*.)

V. Legal Standard

Pursuant to section 13(a)(1)(A) of the Vaccine Act, a petitioner must prove their claim by a preponderance of the evidence. A special master must consider the record as a whole but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). Thus, for example, the Vaccine Act instructs that a special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 300aa-13(b)(2). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Thus, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule is not absolute. Afterall, "medical records are only as accurate as the person providing the

information." *Parcells v. Sec'y of Health & Human Servs.*, No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." 2005 WL 6117475, at *19 (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992)). Importantly, however, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy*, 23 Cl. Ct. at 733 (quoting the decision below).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, a special master must consider the credibility of the individual offering the testimony. *See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence" contained in the record. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417 (concluding that the special master did not err by excluding expert opinion based on facts not substantiated by the record).

VI. Finding as to Onset

There is no dispute that M.R. had confirmed thrombocytopenia, later diagnosed as ITP, when he first presented for testing on January 2, 2018, 56 days post-vaccination. (Ex. P6, p. 472.) However, the date of M.R.'s first presentation for diagnosis and treatment is not the same as the onset of his condition. In particular, M.R.'s January 2 blood test and January 3 follow up with his pediatrician were prompted by a history of bruising. (Ex. P1, p. 32.) Resolving the disputed timing of onset of M.R.'s ITP involves two questions. First, when was the onset of the bruising that ultimately led to M.R.'s presentation for treatment of what was ultimately diagnosed as ITP? Second, does that bruising identify the onset of the ITP? For the reasons discussed below, I conclude that there is preponderant evidence that the bruising for which M.R. was treated occurred within 42 days of vaccination, but not 30 days of vaccination. I further conclude that Dr. Strouse is not persuasive in doubting that the bruising at issue is indicative of the onset of ITP. Accordingly, there is preponderant evidence that M.R. suffered onset of ITP within 42 days of his November 7, 2017 vaccinations.

a. Onset of Bruising

Although petitioner indicates in her affidavit that M.R. began bruising on his lower legs within two weeks of his vaccination, respondent stresses that M.R. had medical encounters of November 22 and December 8, 2017, wherein the bruising was not recorded. (Ex. P1, pp. 30-31.) The December 8 encounter in particular marks the 31st day post-vaccination. Thus, respondent doubts the accuracy of the account. Citing *Kirby v. Secretary of Health and Human Services*, 997 F.3d 1378 (Fed. Cir. 2021), petitioner disagrees, arguing that the silence of these medical records is not dispositive. (ECF No. 46, p. 5.) Petitioner is correct as a general matter that the silence of the medical records is not *necessarily* dispositive; however, unlike the later bruising arising in mid-December, petitioner herself distinguishes this earlier bruising, which was confined to M.R.'s calves, as not concerning. (Ex. P2.)

Even without treating the medical records as definitive evidence that the bruising did not occur, the absence of any notation of bruising in the contemporaneous medical records would still tend to confirm petitioner's recollection that it was not unusual or concerning enough to be reported to M.R.'s physician. Relatedly, because the calf bruises were not brought to medical attention, there is no treating physician opinion available regarding the nature or extent of the bruising and whether it is medically reasonable (even in hindsight) to attribute the bruises to the later-diagnosed ITP rather than M.R.'s toddling. Petitioner's affidavit is the only evidence suggesting that this calf bruising was occurring at all during that time period and even that account doubts (albeit as a lay person) that it was medically relevant. As both petitioner herself and respondent's expert suggest, leg bruising is not necessarily unexpected among toddlers learning to walk. (Ex. A, p. 4.) Thus, even if some calf bruising did occur in the late November to early December timeframe petitioner recalled, there is not preponderant evidence that it was related to M.R.'s later diagnosed ITP.

There is, however, preponderant evidence that a subsequent onset of a more concerning pattern of bruising occurred in "mid-December," which would fall within 42 days of M.R.'s vaccinations, *i.e.*, on or before December 19, 2017. Petitioner's account that a pattern of bruising over a wider area of M.R.'s body began in mid-December is consistent with the medical records. Whereas the calf bruising in November 2017 was not necessarily concerning and did not come to medical attention, petitioner explained that "[i]n the middle of December 2017, [M.R.'s] bruising had started to progress to other parts of his body, particularly his legs, armpits, arms, back of his knees, and along his spine." (Ex. P2, p. 3.) Petitioner explained that this bruising became concerning because M.R.'s twin sister was not experiencing anything similar, despite also learning to walk. (*Id*.) Thereafter, the medical records confirm that petitioner presented M.R. for care on January 3, 2018, specifically due to a prior history of bruising. (Ex. P1, p. 32 (noting history concerning for "burising [*sic*] mainly on legs").)[8] Moreover, the same

[8] Respondent suggests that bruising was not documented by the physical examination at that time (ECF No. 45, p. 19) and it is true that bruising is not specifically noted within the physical exam portion of the record; however, the pediatrician's history of present illness clearly includes actual findings and not just parental reports. In addition to noting bruising, it also reports the results of certain blood tests. (Ex. P1,

pattern of bruising petitioner described in her affidavit was later confirmed as part of M.R.'s subsequent presentation during his physical examination in mid-January. (Ex. P3, p. 12 (physical exam documenting "scattered bruising noted to upper extremities, trunk, and lower extremities").)

The medical treatment records alone do not document a clear period of onset for M.R.'s prior bruising; however, bruising was clearly the reason petitioner initially sought care for M.R. for what was ultimately diagnosed as ITP, meaning that the bruising necessarily predated M.R.'s January 2, 2018 blood test. Moreover, one of the histories provided in the contemporaneous medical records during the course of M.R.'s hospitalization at Children's Hospital of San Antonio on January 15, 2018, explicitly confirms the rationale underlying petitioner's affidavit account. Specifically, that history explained of M.R.'s bruising that "[i]n early January, patient was evaluated by his pediatrician due to a concern for bruising, per mother. Mother was confused because the patient seemed to bruise easily, however his twin sister had never experienced similar bruising." (*Id*. at 10.) This history exactly matches petitioner's explanation in her affidavit as to how she first observed M.R.'s abnormal bruising and then later sought care for that bruising in early January 2018. (Ex. P2.) It therefore offers fairly strong corroboration of petitioner's affidavit regarding the history of bruising. Moreover, even without the benefit of the additional affidavit account, it confirms observation of M.R.'s bruising in comparison to his sister *over time* prior to his first presentation to the pediatrician.[9]

To be sure, the medical records include some seeming inconsistencies and, therefore, do not necessarily support petitioner's recollection uniformly. In particular, respondent stresses a different history provided during the same hospitalization which recorded that "[m]om states that on 1/1/18 she noticed red 'pinpoint perfect circles' over his skin. Patient was taken to his PCP and on 1/2 had blood work done . . . . Mom states rash on skin and bruises that were noted at beginning of month had resolved until last night."[10] (Ex. P3, p. 24.) This would seem to suggest, contrary to her affidavit, that petitioner first noted abnormal bruising on January 1, just the day before seeking care. Importantly, however, the focus of this particular history appears to be the separate rash or rash-like presentation rather than the additionally referenced bruising, and only the rash is explicitly noted as having been observed by petitioner herself on the first of the

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p. 32.) Given that bruising is the only outward symptom discussed in the history of present illness, one would likely expect a more explicit statement if that single presenting symptom were found to be absent upon physical examination.

[9] That is, it reflects petitioner observing (and being confused by) a difference between twin siblings in their propensity to bruise. Naturally, this would suggest observation over the course of time, rather than being consistent with any abrupt onset of abnormal bruising.

[10] After noting that M.R.'s initial bruising had resolved until last night, the same history further notes in the following paragraph that "[m]om states patient has not cried or shown that he was hurting prior to seeing the mouth bleeding. No increased irritability or fussiness. No prior abnormal bleeding or bruising." (Ex. 3, p. 24.) Although somewhat ambiguous, this reference to "no prior abnormal bleeding or bruising" appears to refer to the period immediately prior to his presentation for mouth bleeding (subsequent to the resolution of his prior bruising) rather than contradicting the preceding history within the same record.

month. Otherwise, this history is less clear with respect to the sequence of events. In particular, it is not necessarily clear whether "noted at the beginning of the month" refers to petitioner's own observation or the observation of M.R.'s pediatrician as of his first medical encounter on January 3. In any event, even if the two histories are in tension, the separate history discussed above, which recorded petitioner's confusion that only M.R., and not his sister, was bruising easily, was recorded on the same date at the same facility and is an affirmative account too specific to have been entered merely in error.

On the whole, the record preponderates in favor of a finding that onset of the bruising that ultimately led to M.R.'s presentation on January 3, 2018, began in mid-December of 2017. Onset of a wider pattern of concerning bruising first arising in mid-December is not contradicted by the earlier November 22 and December 8 records and is consistent with petitioner first seeking care for M.R. in very early January. Although the subsequent treatment records are not completely clear with regard to onset, they contain sufficient information to corroborate petitioner's affidavit account.

b. Bruising as the Presenting Symptom of ITP

Both parties' experts agree as a general matter that bruising is a symptom of ITP. (Exs. A, p. 3; P9, p. 4.) Further to this, both M.R.'s treating physicians and petitioner's expert, Dr. Ghose, attribute M.R.'s own history of bruising to his ITP. (Exs. P9, p.7-8; P1, p. 32; P3, pp. 12-13.) Additionally, Dr. Ghose reasons on petitioner's behalf that it would take "weeks" for platelet counts to drop from a normal level to the 51,000 level documented on January 2, 2018. (Ex. P9, p. 8.) Therefore, he opines that it is medically reasonable to conclude that the platelets had dropped below 100,000 (*i.e.*, ITP range) by mid-December. (*Id.*; Ex. P13, pp. 1-2.) This also correlates to when the abnormal bruising began.

Dr. Strouse disagrees with Dr. Ghose's assessment of platelet kinetics, citing Zeller et al. for the proposition that platelet counts in children with ITP "usually" drop suddenly. (Ex. C, p. 2 (citing Bernward Zeller et al., *Childhood Idiopathic Thrombocytopenic Purpura in the Nordic Countries: Epidemiology and Predictors of Chronic Disease,* 94 ACTA PAEDIATRICA 178 (2005) (Ex. A, Tab 12)).) Dr. Strouse also opines ITP is an unlikely cause of M.R.'s own bruising. (*Id.*) He stresses that thrombocytopenia was not documented until January 2, 2018, about 8 weeks post-vaccination. (Ex. A, p. 4.) He further stresses that severe thrombocytopenia was not documented until mid-January of 2018, about 10 weeks post-vaccination. (*Id.*) Dr. Strouse further notes that a platelet count of 51,000 can often be asymptomatic. (*Id.* at 3). There are several problems with Dr. Strouse's line of reasoning.

Dr. Strouse's opinion is in tension with the contemporaneous medical records. Regardless of whether a platelet count of 51,000 *can be* asymptomatic, M.R. was diagnosed with ITP by his pediatrician based on his initial presentation, which included both a platelet count of 51,000 *and* a history of bruising. (*E.g.*, Ex. P1, p. 32.) Moreover, there is no indication any of his treating physicians doubted his bruising was

related to his ITP or felt any other cause for the bruising was implicated. (*Id.*; Ex. 3, p. 12-13 (noting bruising and indicating M.R.'s "past medical history and current presentation [are] consistent with immune thrombocytopenia of childhood") Notably, while Dr. Strouse attributes leg bruising to M.R.'s learning to walk, he offers no alternative explanation for the wider pattern of bruising that occurred later. However, as discussed above, that bruising was concerning enough to cause petitioner to seek medical treatment for M.R. Thus, if M.R.'s bruising was not considered a symptom of his ITP, another explanation would have been warranted as part of his medical evaluations. In fact, M.R.'s medical records imply that it was only the fact of M.R.'s ITP that gave his treaters comfort that there was no child abuse to report. (Ex. P3, p. 5.) M.R.'s hospital records note of his initial ED presentation of January 14 that M.R. "was noted to have petechiae on his neck and face, as well as bruising to areas on his forehead arms, trunk, and lower extremities. The[y] initially questioned mom *with concern*, however she reported that he has been seeing his pediatrician since early January to evaluate the bruising." (*Id.* (emphasis added); *see also* admission data at pp. 83, 88 (identifying bruising under problems, but marking "no" for unexplained bruising).)

Additionally, January 2, 2018, is merely the first time M.R.'s platelets happened to be measured during the relevant period. Accordingly, even if one preferred Dr. Strouse's assessment of platelet kinetics over that of Dr. Ghose, the date of the test result does not in itself imply the date of the drop in platelet counts. Regardless of whether the initial drop occurred suddenly or over the course of weeks, Dr. Strouse provides no rationale for divorcing the drop in platelets from the outward presentation of symptoms consistent with ITP. Dr. Strouse offers a discussion that suggests M.R.'s own initial pattern of mild platelet deficiency is better viewed as consistent with viral suppression. (Ex. C, p. 2.) However, based on my review of that discussion, this point speaks to the underlying cause of M.R.'s ITP more so than the timing of its onset. Thus, while that may be a consideration in the ultimate causal analysis, it does not suggest that the timing of onset is other than what is reflected in M.R.'s medical records and petitioner's affidavit.

Dr. Strouse stresses the difference between M.R.'s January 2 platelet count and his mid-January platelet count to seemingly implicate a sudden platelet drop occurring around that specific time that distinguishes M.R.'s later more severe thrombocytopenia from his earlier mild presentation. (Ex. A, p. 3; Ex. C, p. 1.) However, the significance of select platelet counts is not at all clear given the documented fluctuations in M.R.'s platelet counts over time. After M.R.'s platelet count was initially measured at 51,000, it was rechecked two days later and was higher at 97,000. (Ex. P6, pp. 450, 472.) Only after that did it drop to 4,000 by January 14, 2018. (Ex. P3, p. 5.) Thereafter, as discussed extensively in the factual summary above, M.R.'s platelet counts fluctuated throughout his entire treatment history. Dr. Strouse has filed literature explaining that "[a]lmost all patients have fluctuations in their platelet count" and that "[r]ecognition that the platelet count is less important than overall bleeding symptoms" has improved care. Nichola Cooper, *State of the Art - How I Manage Immune Thrombocytopenia,* 177 BRIT. J. HAEMATOLOGY 39, 39, 48 (2017) (Ex. A, Tab 5, pp. 1, 10). Thus, it is difficult to see

how the drop in platelets between January 2 and January 14 could be informative of the initial onset of M.R.'s ITP given the overall fluctuations.

Finally, contrary to what Dr. Strouse suggests, the Zeller et al. study does not actually address platelet kinetics upon condition onset. *See* Zeller et al., *supra* Ex. A, Tab 12. The Zeller et al. study was a prospective study examining the clinical courses of 423 children with ITP over six months. *See id.* at 1. Subjects were brought into the study if they were diagnosed with ITP under conventional diagnostic criteria and had at least one prior platelet measurement that indicated the need for therapy. *See id.* at 2. Nothing in the study is readily identifiable as an analysis of pre-diagnosis platelet trajectories. When the study refers to sudden versus insidious onset, it is referring to *symptom* onset. Zeller et al. indicates that an "insidious" onset of symptoms (defined as symptom duration of over two weeks prior to diagnosis) is "strongly associated" with the chronic form of ITP, *id.* at 5-6, which both experts agree M.R. ultimately suffered. (Exs. P9, p. 7; A, p. 4.) Thus, I do not view the Zeller study as refuting Dr. Ghose's opinion with respect to onset.

VII. Conclusion

In light of all of the above, the evidence preponderates in favor of a finding that abnormal bruising was the first symptom of M.R.'s ITP and that onset of the condition occurred no earlier than 31 days post-vaccination but within 42 days post-vaccination.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master